K110891
p. 1 of 3

**SECTION 5: 510(k) SUMMARY** SEP 13 2011

| | |
|---|---|
| **Submitter:** | LeMaitre Vascular, Inc.<br>63 Second Avenue<br>Burlington, MA 01803 |
| **Contact Person:** | Andrew Hodgkinson<br>Vice President, Clinical, Regulatory and Quality Affairs<br>Phone: 781-221-2266 x108<br>Fax: 781-425-5049<br>Email: ahodgkinson@lemaitre.com |
| **Date Prepared:** | 9/13/2011 |
| **Trade Name:** | The UnBalloon Non-Occlusive Modeling Catheter |
| **Common Name:** | Modeling Catheter |
| **Classification Name:** | Percutaneous Catheter |
| **Predicate Devices:** | Cook Coda Balloon Catheter - K032869<br>Medtronic Reliant Balloon Catheter - K050038<br>Gore Tri-Lobe Balloon Catheter - K033670 |
| **Device Description:** | The UnBalloon Non-Occlusive Modeling Catheter consists of an expandable Nitinol mesh in a 14F retractable sheath. The Nitinol mesh design allows for expansion without occluding blood flow. The Nitinol mesh and radiopaque markers are highly visible under fluoroscopy and assist in the positioning of the device. The inner lumen allows for a 0.035 or 0.038 inch guidewire for over-the-wire access. Side ports and clear handle/luer allow the device and guidewire lumen to be flushed. The blue handle allows the device to be sheathed/unsheathed while the clear handle/luer controls the expansion of the Nitinol mesh. |
| **Intended Use:** | The UnBalloon Non-Occlusive Modeling Catheter is intended to assist in the modeling of self-expanding endoprostheses in large diameter vessels. |
| **Summary of Technological Characteristics:** | The UnBalloon is a percutaneous catheter designed to assist in modeling of self-expanding endoprostheses without obstructing blood flow. This device differs from the predicate devices as it is designed to eliminate the pressure that typically builds up on the proximal end of those devices when inflated. By eliminating occlusion (or partial occlusion), the risks associated with occlusion during ballooning of an endovascular prosthesis may be minimized, potentially allowing the surgeon to more accurately model grafts that have been deployed. |

| | |
|---|---|
| **Summary of Product Testing:** | The following has been assessed through product characterization and validation:<br><br>*Worst case Simulated use*<br>*Inflation/Deflation time*<br>*Freedom from leakage*<br>*Kink resistance*<br>*Fatigue*<br>*Hemostasis*<br>*Bond tensile strength*<br>*Radial outward force*<br>*Compatibility with endoprostheses*<br>*Physiological insult – animal testing (Acute and 28-day)* |
| **Summary of OUS Post Market Surveillance** | Between 14-June-2011 and 16-August-2011, LeMaitre Vascular attended 13 cases in Brazil and the European Union using the UnBalloon Non-Occlusive Modeling Catheter. In all cases we achieved technical success with no reported adverse events or device related malfunctions. The device performed successfully in 4 thoracic cases and 9 abdominal cases using a variety of stent grafts. The endoprostheses that were modeled included the LeMaitre TAArget (n=1, 8%); Gore Excluder (n=1, 8%); Cook Zenith TX2, Proform (n=2, 16%); Medtronic Endurant (n=1, 8%); Jotec E-Vita (n=2, 16%); Gore TAG or C-TAG (n=1, 8%); Aorfix (n=1, 8%) and 1 (8%) unknown. Devices ranged in size from 24mm to 40mm at the most proximal diameter.<br>The UnBalloon was used to enhance primary attachment in the landing zone (n=8; 62%) while it was used 1 time (8%) to successfully treat a type 1a endoleak. Other uses included: Enhancement of Primary Attachment Zone + Modeling of device overlap (n=2; 15%); Modeling of Mainbody (n=1; 7.7%); Modeling of overlapping zone (n=1; 7.7%).<br>The UnBalloon was deployed a median 3 times per case with mean deployment time of 36.6 sec +/- 39.2sec (Range 5 - 110sec.).<br>Blood loss through the device was minimal with only 1 recorded result of 3ml that emanated through the guidewire lumen as expected.<br>Radiopacity received an overall rating of 'good' in most cases with 2 cases relaying some difficulty seeing the inner marker bands or sheath marker.<br>The applied modeling force (radial force) was estimated as "appropriate" in 8 (62%) cases while 5 (37%) rated it as "unknown/cannot judge."<br>No device failures were reported in any case. The Nitinol cage was resheathed in all cases without any issues and there were no reports of the Nitinol cage getting hooked or caught in any Endovascular devices. No other complications or adverse events were reported.<br><br>These initial clinical results indicate that the UnBalloon Non-Occlusive Modeling Catheter performs as intended and is as safe and effective as the predicate devices. |

| | |
|---|---|
| **Summary of Pre-clinical Study:** | The biocompatibility of the device was tested per ISO10993-1. |
| **Conclusion:** | LeMaitre Vascular has demonstrated that The UnBalloon Non-Occlusive Modeling catheter is substantially equivalent to the predicate devices based on its indications for use and fundamental scientific technology. |

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

LeMaitre Vascular, Inc.
c/o Mr. Andrew Hodgkinson
Vice President, Clinical, Regulatory and Quality Affairs
63 Second Avenue
Burlington, MA 01803

SEP 13 2011

Re: K110891
Trade Name: UnBalloon Non-Occlusive Modeling Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II (two)
Product Code: DQY
Dated: August 30, 2011
Received: August 31, 2011

Dear Mr. Hodgkinson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

**SECTION 4: INDICATION FOR USE STATEMENT**

510(k) Number : K110891

Device Name: The UnBalloon Non-Occlusive Modeling Catheter

**Indications for Use:**

The UnBalloon Non-Occlusive Modeling Catheter is intended to assist in the modeling of self-expanding endoprostheses in large diameter vessels.

Prescription Use____X____ and/or Over-The Counter Use_____

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE ID NEEDED)

---

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K110891